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Bone densitometry: influence of prosthetic design and hydroxyapatite coating on regional adaptive bone remodelling

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Abstract The objective of this prospective study was to determine if bone densitometry can detect disparities in regional adaptive bone remodelling surrounding the cementless porous-coated femoral component of a hip prosthesis in two titanium alloy implants of different design . These prostheses were the S-ROM™ (*n*=69) and the Multilock™ (*n*=65). The Multilock™ implants consisted of two groups; 25 had a 50 micron layer of hydroxyapatite (HA) sprayed over the porous surface of the femoral component and the remaining 40 femoral components were not coated with HA. Densitometry was performed with dual energy X-ray absorptiometry (DXA) utilizing the LUNAR ORTHO™ software to analyse the seven Gruen zones. Bone mineral density measurements were obtained within a week of surgery as a baseline reference and at 6, 12, 24, 36 and 48 months thereafter. At 6 months there was significant mineral loss in all Gruen zones in the three prostheses. By 48 months there were differences in mineral loss between the three prostheses. In the zones adjacent to the porous surface, predominantly zones 1 and 7, the S-ROM™ exhibited 60% less mineral loss than the Multilock™ in zone 1, and there was no significant difference in zone 7. Compared to the Multilock-HA, the S-ROM lost 35% less mineral in zone 1, but the Multilock™ lost 70% less mineral than the S-ROM™ in zone 7. The Multilock-HA lost 37% and 75% less mineral than the Multilock in zones 1 and 7, respectively, i.e., hydroxyapatite coating tended to preserve bone stalk. Using the Gruen zone area measurements provided by the software, the S-ROM had significantly greater bone resorption in zone 7 at 24 months than either of the Multilocks, which did not differ from each other. In conclusion, DXA has shown differences in periprosthetic adaptive bone remodelling between implants of different design and composition as a function of time.

Résumé Cette étude prospective visait à comparer le remodelage osseux local d'adaptation entourant la pièce fémorale, à revêtement poreux et sans ciment, de deux prothèses de hanche de conception différente, formées d'un alliage de titane. Il s'agissait des prothèses S-ROM^{MC} (*n*=69) et Multilock^{MC} (*n*=65). Les patients qui ont reçu la prothèse Multilock^{MC} se divisaient en deux groupes: chez 25 d'entre eux, la partie fémorale à revêtement poreux de la prothèse a été enduite d'une couche d'hydroxyapatite (HA) de 50 m et chez les 40 autres, la composante fémorale ne comportait pas ce type de revêtement. On a effectué un examen densitométrique par absorptiométrie biphotonique à rayons X au moyen du logiciel LUNAR ORTHO^{MC} en vue d'analyser les sept zones de Gruen. Des mesures de la densité minérale osseuse ont été réalisées moins d'une semaine après la chirurgie pour déterminer les valeurs de référence initiales et après 6, 12, 24, 36 et 48 mois. On a observé une perte minérale importante après 6 mois, dans toutes les zones de Gruen, pour les trois types de prothèse. Après 48 mois, on a noté des différences quant à la baisse du contenu minéral osseux, entre les trois types de prothèse, dans les zones adjacentes à la surface poreuse, surtout dans les zones 1 et 7. Ainsi, avec la prothèse Multilock^{MC}, la perte minérale dans la zone 1 a été supérieure de 60% à celle notée avec la prothèse S-ROM^{MC}, mais on n'a observé aucune différence significative dans la zone 7. Avec la prothèse S-ROM^{MC}, la perte minérale observée dans la zone 1 a été inférieure de 35% à celle notée avec la

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prothèse Multilock-HA, mais elle a dépassé de 70% celle notée avec la prothèse Multilock dans la zone 7. Avec la prothèse Multilock, la perte minérale dans les zones 1 et 7 a été supérieure de 37% et de 75%, respectivement, à celle notée avec la prothèse Multilock-HA. Ainsi, le revêtement d'hydroxyapatite tend à préserver le tissu osseux. Si l'on se fie aux mesures des zones de Gruen obtenues à l'aide du logiciel, la résorption osseuse dans la zone 7 après 24 mois a été beaucoup plus importante avec la prothèse S-ROM qu'avec les prothèses Multilock, et ces dernières ne présentaient pas de différence l'une par rapport à l'autre. En conclusion, l'absorptiométrie biphotonique à rayons X constitue une méthode appropriée pour évaluer le remodelage osseux adaptatif en fonction du temps avec des prothèses de conception et de composition différentes.

Introduction

The advent of dual-energy X-ray absorptiometry (DXA) has enabled accurate and reproducible quantification of periprosthetic bone and its changes as a function of time [7, 8]. Compared to the standard radiograph, DXA is more sensitive in the disclosure of small bone mineral changes, and quantitative computed tomography is disadvantaged by the production of a large amount of beam diffraction by the metal prosthesis which interferes with the measurement [25]. The attributes of DXA are conducive to monitoring regional adaptive remodelling of porous-coated cementless femoral implants of different designs and composition. Initial reports on the application of DXA were concerned with the determination of the natural history of bone remodelling in asymptomatic patients with normal hip implants. These were mainly based on cross-sectional retrospective analyses, and in those studies that were prospective serial repeated measurements were usually terminated at two years post-implantation [9, 11, 12, 14–17, 26]. There are few communications dealing with the influence of prosthesis design and composition on regional adaptive bone remodelling [6,10, 20, 24, 27].

We report the results of a 4-year prospective study of adaptive remodelling in two types of cementless porous-coated femoral implants, of which one had a subset of hydroxyapatite coating over the porous surface.

Materials and methods

Bone mineral density (BMD, g/cm^2) for the seven Gruen Zones surrounding the femoral component were determined by dual energy X-ray absorptiometry (DXA) employing the LUNAR DPX scanner and LUNAR ORTHO™ software (LUNAR Corporation, Madison, WI, USA) [5].

Two femoral prosthesis designs of titanium alloy composition were studied; the Multilock™ (Zimmer, Warsaw, IN, USA) and the S-ROM™ (Johnson & Johnson, Raynham, MA, USA). The Multilock femoral component is porous-coated proximally and fluted distally, whereas the S-ROM, a modular femoral implant, consists of a proximally porous-coated sleeve and a stem that is fluted and slotted distally (Figs. 1, 2)

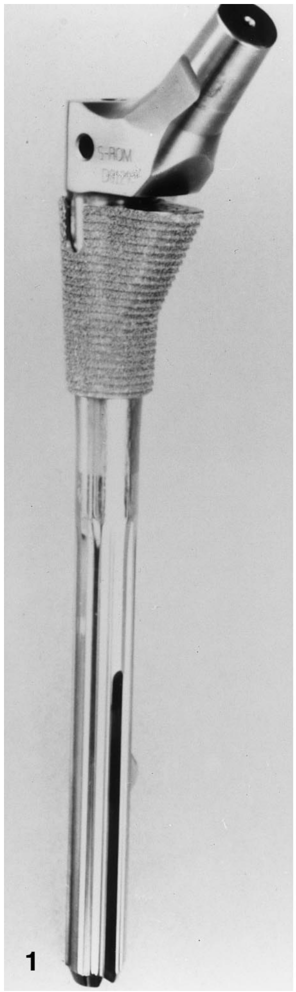

Fig. 1 S-ROM™ prosthesis consisting of a porous-coated sleeve proximally and a fluted and slotted stem distally. Titanium alloy

Fig. 2 Multilock™ prosthesis. Porous-coated proximally and fluted stem distally. Titanium alloy

Baseline measurements of the seven Gruen zones were obtained within one week of surgery to serve as the reference for calculating percentage change over time. The protocol for the S-ROM patients stipulated repeated measurements at 3, 6, 9, 12, 18 and 24 months, and yearly thereafter. In order to reduce patient inconvenience the frequency of follow-up DXA measurements in the Multilock patients was changed to 6 months, 12 months, and yearly thereafter. There were 69 S-ROM patients with at least 4 follow-up measurements and 65 patients with Multilock prostheses who had at least 3 follow-up measurements. Not all patients met all time points. These groups were analysed statistically by single-factor analysis of variance for repeated measurements with missing observations (NCSS 97, Kayesville, UT, USA). Of the 65 patients with Multilock implants, 25 had a 50 micron thick coating of hydroxyapatite-tricalcium phosphate (HA) sprayed over the porous surface and 40 were without HA coating.

It has been observed by radiography that there can be a considerable loss of bone volume in the calcar, aside from mineral depletion per se [18]. To quantify this observation the percent change in area of the medial femoral cortex encompassed by Gruen zone 7 was calculated from the areal values which were measured by the ORTHO™ edge detection software and presented in the bone density report. These changes were compared in the three prostheses.

Table 1 Mean percent change in BMD and the 95% confidence interval limits in the seven Gruen zones for each prosthesis from 6 months to 48 months

Gruen Zone	Months	S-ROM mean %change (95% CIL)	Multilock mean %change (95% CIL)	Multilock-HA mean %change (95% CIL)
1	6	–9.2 (–10.6, –7.7)	–20.9 (–24.6, –17.4)	–17.9 (–20.7, –15.2)
	12	–9.2 (–10.6, –7.7)	–22.9 (–26.7, –19.1)	–16.6 (–18.9, –14.3)
	24	–7.4 (–9.3, –5.4)	–23.1 (–27.3, –18.8)	–16.6 (–19.4, –14.5)
	36	–7.6 (–9.7, –5.4)	–23.8 (–28.9, –18.8)	–16.1 (–19.8, –12.5)
	48	–10.4 (–14.7, –6.3)	–25.4 (–33.7, –17.7)	–15.9 (–20.3, –11.7)
2	6	–11.5 (–12.9, –10.0)	–13.5 (–15.6, –11.5)	–11.8 (–13.8, –9.8)
	12	–11.6 (–13.1, –10.2)	–15.7 (–17.9, –13.6)	–11.4 (–13.1, –9.8)
	24	–10.9 (–12.9, –8.9)	–15.4 (–17.8, –13.0)	–10.4 (–12.1, –8.6)
	36	–7.9 (–10.1, –5.7)	–12.5 (–15.4, –9.5)	–10.9 (–13.5, –8.3)
	48	–12.1 (–16.3, –8.0)	–11.7 (–16.4, –7.0)	–10.9 (–13.9, –7.9)
3	6	–7.5 (–8.6, –6.0)	–7.1 (–8.6, –5.5)	–4.9 (–6.5, –1.8)
	12	–5.9 (–7.0. –4.7)	–6.3 (–8.0, –4.7)	–3.2 (–4.5, –1.8)
	24	–3.4 (–5.0, –1.9)	–6.5 (–8.3, –4.6)	–1.5 (–2.9, –0.4)
	36	–3.0 (–4.8, –1.3)	–3.9 (–6.1, –1.7)	–3.0 (–5.2, –0.8)
	48	–7.4 (–10.7, –4.2)	–2.4 (–6.0, 1.3)	–1.8 (–4.3, 0.7)
4	6	–5.4 (–6.6, –4.1)	–6.1 (–7.6, –4.7)	–5.3 (–7.2, –3.3)
	12	–6.0 (–4.7, –1.2)	–6.9 (–8.4, –5.3)	–3.7 (5.3, –2.1)
	24	–2.0 (–3.8, –0.2)	–4.7 (–6.5, –3.0)	0.2 (–1.5, 1.9)
	36	1.4 (–0.5, 3.4)	–2.8 (–4.9, –0.7)	0.9 (–1.6, 3.5)
	48	–0.6 (–4.3, 3.2)	–1.3 (–4.7, 2.1)	3.4 (0.5, 6.4)
5	6	–4.4 (–6.1, –2.6)	–3.5 (–5.6, –1.4)	–1.6 (–4.5, 1.2)
	12	–3.0 (4.7, –1.2)	–0.9 (–3.0, 1.3)	–2.6 (–5.0, 0.2)
	24	1.0 (–1.4, 3.4)	1.2 (–1.2, 3.6)	–1.6 (–4.1, 0.9)
	36	0.8 (–1.9, 3.5)	1.0 (–1.9, 3.9)	–2.1 (–5.9, 1.8)
	48	1.5 (–3.6, 6.6)	3.8 (–0.9, 8.6)	4.3 (–0.1, 8.7)
6	6	–10.7 (–12.1, –9.4)	–8.9 (–10.9, –7.0)	–8.3 (–11.0, –5.7)
	12	–10.0 (–11.3, –8.7)	–8.8 (–10.9, –6.8)	–5.8 (–8.1, –3.6)
	24	–7.4 (–9.2, –5.6)	–6.4 (–8.7, –4.1)	–1.8 (–4.1, 0.6)
	36	–4.4 (–6.5, –23)	–3.2 (–5.9.–0.4)	–1.5 (–5, 2.0)
	48	–4.4 (–8.3.–0.5)	–1.2 (–5.7, 3.3)	–0.6 (–3.5, 4.7)
7	6	–17.3 (–19.2, –15.4)	–15.8 (–18.6, –12.9)	–13.1 (–16.1, –10.0)
	12	–21.6 (–23.5, –19.7)	–18.3 (–21.3, –15.3)	–12.5 (–15.1, –9.9)
	24	–16.8 (–19.4, –14.3)	–19.7 (–23.1, –16.4)	–11.3 (–14.0, –8.6)
	36	–17.3 (–20.2, –14.4)	–18.6 (–22.6, –14.6)	–10.9 (–15.0, –6.8)
	48	–18.6 (–24.1, –13.1)	–22.1 (–30.4, –13.8)	–5.6 (–10.4, –0.9)

In the S-ROM group there were 38 women and 31 men with an average age of 61 years (range, 26 to 80 years). There were 22 women and 43 men with Multilock implants and their average age was 63 years (range, 43 to 80 years). Osteoarthritis was the indication for total hip arthroplasty in over 80% of the patients in both groups.

Inclusion criteria required that the patient be asymptomatic with a Harris hip score ≥95, have a primary implant with no osteotomy of the greater trochanter, nor bone graft application, fractures during surgery, radiographic evidence of subsidence and other complications during follow-up. All patients remained non-weight bearing for 6 weeks post-surgery, with progressive weight bearing thereafter as tolerated.

Results

Table 1 details the means of the percent BMD change and their 95% confidence interval limits (CIL) for the S-ROM, Multilock and Multilock-HA prostheses from 0 to 48 months post-implantation for the seven Gruen zones. Fig. 3 is a composite graph derived from Table 1 illustrating the temporal percent BMD changes in those three prostheses.

A significant BMD loss was registered in all Gruen zones for the three prostheses, at 6 months and at 48 months mineral recovery was observed in Gruen zones 4 and 5 for the S-ROM, zones 3, 4 and 5 for the Multilock, and zones 3, 4, 5 and 6 for the Multilock-HA as judged by the absence of a significant difference from the baseline reference values.

Differences were present between the three prostheses at 48 months. S-ROM versus Multilock: Significantly lower mineral loss for S-ROM in zone 1, but a greater loss in zone 3. S-ROM versus Multilock-HA: Significantly lower mineral loss for S-ROM in zone 1, but greater losses in zones 3, 4, 6 and 7. Multilock versus Multilock-HA: Significantly greater losses for the Multilock in zones 1, 4 and 7. Specifically, in the regions adjacent to the porous surface, i.e., Gruen zones 1 and 7, the Multilock exhibited mineral losses that were greater than Multilock-HA by a factor of 1.6 and 3.9, respectively.

Table 2 lists the mean changes in the projected area of Gruen zone 7, the calcar region, between 0 and 24 months. It was found that the mean loss in area of the S-ROM was 12.9% which was significantly greater than

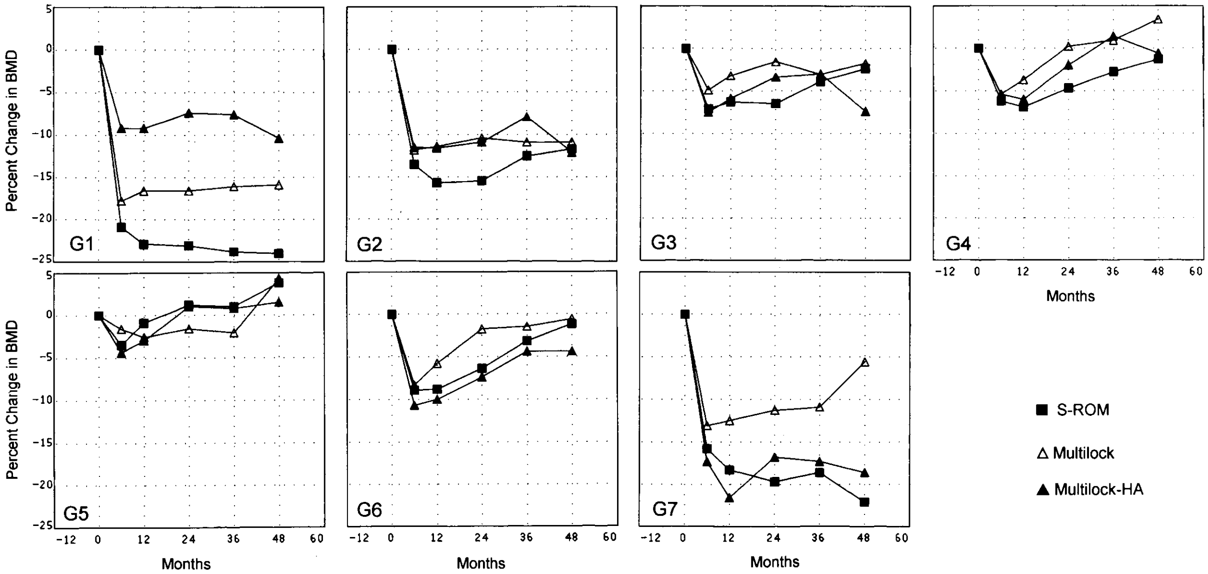

Fig. 3 Graphs of the percent change in BMD as a function time in the 7 Gruen zones for the S-ROM™, Multilock™ and Multilock-HA™ implants

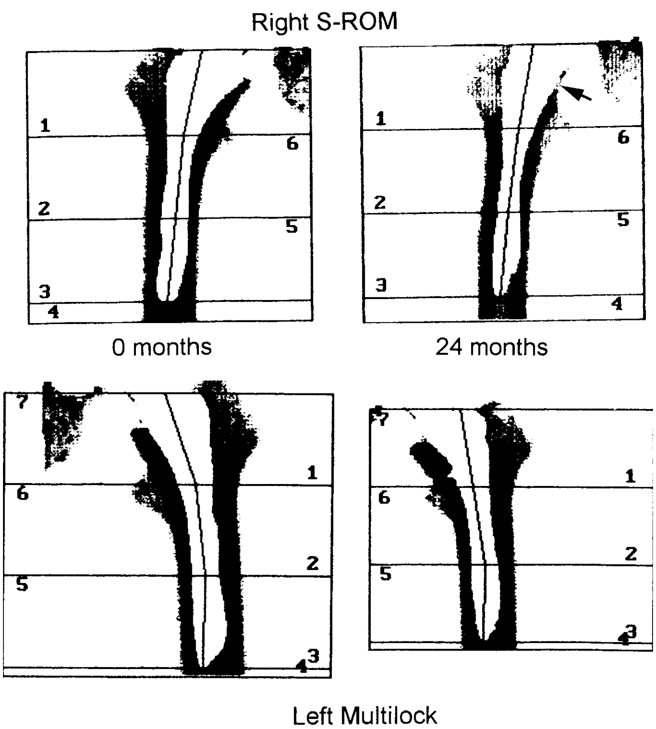

Fig. 4 R-SOM™ and Multilock™ hip prostheses. Comparison of the baseline (0 month) and 24 month Gruen zone BMD measurements. Note the bone resorption at 24 months of the medial femoral cortex in Gruen zone 7 of the right S-ROM™ (arrow), and the small increase in the left Multilock™

the losses of 4.4% and 4.1% obtained for the Multilock and Multilock-HA, respectively. There was no significant disparity between Multilock and Multilock-HA implants (Fig. 4). The other Gruen zones showed variable changes in area over the time period, but they were not large nor significantly different between the three prostheses. There was no correlation between the %BMD change and the %area change within each prosthesis type.

Table 2 Percent change in area between 0 and 24 months post-implantation in Gruen zone 7

	S-ROM %change	Multilock %change	Multilock-HA %change
Mean	–12.9	–4.4	–4.1
95% CIL	–18.1, –7.6	–9.5, 0.8	–10.3, 2.1
Range	–58.8 to 11.6	–28.9 to 13.8	–30.3 to 20.6

Discussion

A mean precision error of 1.7% was obtained in 9 implanted cadaver femora scanned ex vivo. The same study showed there was a variation of 5% in the measurements between 15 degree internal and 15 degree external rotation of the cadaver femora. This indicates that small rotations from the neutral hip position, as recommended for scanning patients, do not cause appreciable errors in cross-sectional and longitudinal studies [13]. In vivo precision errors range from 2.6% to 5%, and differences exceeding 0.16 g/cm^2 can be resolved with confidence [7, 21]. These results favour the ability of DXA to disclose significant mineral changes when they occur in periprosthetic bone.

The ongoing prospective investigation presented here clearly show differences in regional adaptive remodelling between the two titanium alloy prostheses of different design, viz., S-ROM and Multilock. Also, the comparison of the Multilock implants with and without hydroxyapatite coating demonstrated that hydroxyapatite significantly reduced the mineral loss in the Gruen zones 1 and 7 which surround the porous coating [20]. The differences in adaptive bone remodelling between the designs is a reflection of femoral stress shielding, which in turn is influenced by a number of factors [1, 4]. Hydroxyapatite has demonstrated increased rate and extent of bone osteointegration experimentally, but the precise mechanism of this induction is speculative [2, 3, 22, 23].

The DXA software is capable of quantifying the Gruen zone areas as a function of time. This is particularly important for the medial femoral cortex in Gruen zone 7, where variable amounts of bone resorption are discernible by conventional radiography [18] a notable difference between the S-ROM and Multilock was observed. The S-ROM registered a mean areal loss of 12.9% at 24 months and it ranged from a loss of 58.8% to a gain 11.6%. These percent changes in area are greater when translated into bone volume. The BMD values do not reflect bone resorption; they are a measure of the mineral density of the remaining unresorbed bone. To assess bone resorption, or expansion, analysis of the standard radiograph or the areas given in the bone densitometry report are required.

Periprosthetic bone mineral determinations of porous-coated femoral hip implants can be obtained with good precision and the technique facilitates a noninvasive assessment of adaptive bone remodelling. It has been demonstrated prospectively in this report that regional bone remodelling can vary with the design of the prosthesis and the presence of hydroxyapatite coating, which tends to lessen mineral loss. This can be extended to the investigation of prosthesis composition and other factors that may influence bone remodelling. As of now, DXA is primarily a research modality.

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